

Fuzeon® (enfuvirtide powder for injection) Prior Authorization Criteria

Fuzeon (enfuvirtide 108 mg lyophilized powder for injection) will be restricted for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, in treatment-experienced patients with HIV-1 replication despite ongoing antiretroviral therapy.

Approval Criteria:

- 1. Clinically diagnosed HIV-1 infection
- 2. Age greater than 6 years
- 3. Most recent viral load (within the past 3 months) > 1000 copies/mL
- 4. Most recent CD4 count (within the past 3 months) < 500 cells/mm³, or history of opportunistic infection
- 5. Resistance testing (within the past 3 months) and, based on test results, a medically appropriate 3-drug regimen cannot be constructed utilizing drugs OTHER than Fuzeon
- 6. Use during pregnancy may be based on expert advice

Test results must be provided in order to meet approval criteria and ensure appropriate use

Approval will be given for a 12-month period.

Fuzeon will not be approved if:

- 1. Fuzeon is initial therapy
- 2. Patient is not resistant to other therapies
- 3. Patient has undetectable levels of HIV